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PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Agri-Mek 0.15 (Avermectin)

COMPANY NAME Merck Sharp and Dohme

SUBMISSION PURPOSE Proposed Registration for Use on Celery

Shaughnessey Code	Chemical and Formulation	% A.I.
<u>122804</u>	<u>Abamectin</u>	<u> </u>
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ECOLOGICAL EFFECTS BRANCH REVIEW

100 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

The registrant, Merck Sharp and Dohme, propose registration of Agri-Mek 0.15 (Avermectin) for use on celery.

100.2 Formulation Information

Agri-Mek 0.15 EC is an emulsifiable concentrate of 2% Avermectin B₁. One gallon contains 0.15 pounds avermectin B₁. Avermectin B₁ is a mixture of avermectins containing \geq 80% avermectin B_{1a} (5-0-demethyl avermectin A_{1a}) and \leq 20% avermectin B_{1b} (5-0-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl) avermectin A_{1a}).

100.3 Application Methods, Direction, Rates

Mix with water at 8.0-16.0 fl. oz./acre and apply by ground equipment as a foliar spray to ensure good upper and lower leaf coverage. Use 8 fl. oz./acre for low to moderate infestations and 16 fl. oz./acre for severe infestations. For spider mites, apply when mites first appear and repeat as necessary to maintain control. For leaf miners, apply when adult flies are first observed and repeat applications at 7-day intervals or as necessary to maintain control.

- Do not apply more than 160 fl. oz. on a given celery crop during its full cropping period.
- Do not apply within 7 days of harvest.

May be applied without a wetting agent or the non-ionic surfactant Leaf Act 80A is recommended to improve foliage wetting and to smooth out spray deposits.

The maximum application rate is 0.02 lb. ai/acre not to exceed 0.20 lb. ai./acre in a growing season for celery.

100.4 Target Organism

Target organisms of Agri-Mek 0.15 are Liriomyza leafminers, twospotted spider mites, and carmine spider mites on celery.

100.5 Precautionary Labeling

The following statements would be on the label:

This pesticide is toxic to fish and wildlife. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.

Do not apply when weather conditions favor drift from target area.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

Do not apply this product through any type of irrigation system.

101 Hazard Assessment¹

101.1 Discussion

The maximum application rate is 0.02 lb. ai./acre. The maximum number of applications would be 10 per growing season at an unspecified interval, except that a 7-day interval is recommended for leaf miner infections. Avermectin is not to be applied within 7 days of harvest. The maximum application is not to exceed 0.20 lb. ai./acre in a growing season for celery.

According to 1982 agriculture census data, principal states for celery production (with percent of acres in U.S.) are California (59%) and Florida (24%). The next highest state for celery production is Michigan with 9% of U.S. production. These three states account for 92% of the celery production in the U.S.² Other states include Texas (2%), New York (2%), Ohio (1%), Pennsylvania and Hawaii (each with < 1%), and other all other states accounting for 2% of production. Most of the celery acreage is irrigated².

Celery is generally grown on sandy-loam or muck soils (>20% OM) in Florida, muck soils in northern states, and mineral to alluvial soils with ca. 1 to 3% organic content in California. Ideal soil is loose, friable, well drained, holds water well, has a pH of 6

¹ Some information taken from previous reviews on tomatoes (Sec. 18 in Florida - 3/8/88) and citrus (3/17/88) where applicable.

² Keitt, G. W., Jr. 1986. Qualitative Use Assessment of Prometryn (080805). U.S. EPA, Benefits and Use Division, Wash., D.C.

to 6.8, and is low in salt ².

Culture of celery is primarily direct seeding or transplanting in California, and transplanting exclusively in Florida, Michigan, Wisconsin, Ohio, and Hawaii. Since most celery is transplanted, use of avermectin could be expected to begin soon after transplanting.

Celery is able to withstand cool weather and is generally grown in the fall and winter months in the more southern latitudes. Winter celery production predominates in Florida and southern California (San Diego Co.), progressing to winter and spring crops in Ventura and Orange Cos. in California. Summer and fall crops are grown in counties further north in California. Michigan crops are harvested in late summer and early fall (August-October) ². In Florida, the average growing season is 80-115 days.

Application of herbicides is needed to control weeds. Cultural practices for celery in Florida include alternate flooding and drying of fields to germinate residue weed species for weed control with multiple cultivation during fallow periods, growing cover crops, and deep cultivation ³.

101.2 Likelihood of Adverse Effects on Nontarget Organisms

The following summarizes the known toxicity information on avermectin:

Acute Tests

Bobwhite quail	LD ₅₀ > 2000 mg/kg
Mallard duck	LD ₅₀ = 85 mg/kg
Bobwhite quail	LC ₅₀ = 3102 ppm
Mallard duck	LC ₅₀ = 383 ppm
Mouse	LD ₅₀ = 13-23 mg/kg
Nonpolar metabolite	LD ₅₀ > 48 mg/kg
Polar metabolite	LD ₅₀ > 5000 mg/kg
Rat	LD ₅₀ = 10-12 mg/kg
Weanling	LD ₅₀ = 1.5 mg/kg

³ Keitt, G.W., Jr. and R.F. Torla. 1986. Florida request for Emergency Exemption of Fluazifop-Butyl on Celery and Lettuce (86-FL-10,11). July 23, 1986 Memorandum. U.S. EPA, Benefits and Use Division, Wash., D.C.

Acute Tests (continued)

Bluegill	LC ₅₀ = 9.6 ppb
Rainbow trout	LC ₅₀ = 3.2 ppb
Channel catfish	LC ₅₀ = 24 ppb
Carp	LC ₅₀ = 42 ppb
<u>Daphnia magna</u>	LC ₅₀ = 0.22-0.34 ppb
Degradates	
Avermectin B ₁ a	LC ₅₀ = 0.42 ppb
Polar metabolite	LC ₅₀ = 4.2 ppb
Moderately polar metabolite	LC ₅₀ = 6.3 ppb
Nonpolar metabolite	LC ₅₀ = 25.4 ppb
Thin-film polar metabolite ⁴	LC ₅₀ = 76.7 ppb
8 a-hydroxy avermectin B ₁ a ⁵	LC ₅₀ = 25.5 ppb
Mysid shrimp	LC ₅₀ = 0.2 ppb
Sheepshead minnow	LC ₅₀ = 15 ppb
Oyster embryo-larvae	LC ₅₀ = 430 ppb
Earthworm (<u>Eisenia foetida</u>)	LC ₅₀ = 18 ppm 28-day 33 ppm 14-day 62 ppm 7-day

Chronic Tests

Rat 1-generation Reproduction	NOEL = 0.05 mg/kg/day (0.5 ppm ⁶) LEL = 0.2 mg/kg/day (1 ppm ⁶)
Rat 1-generation Reproduction	NOEL < 0.5 mg/kg/day (2.5 ppm ⁶) (decreased pup survival, delay in eye-opening)

⁴ This polar metabolite is the last one formed and is what the parent becomes after 27 hours.

⁵ Major soil metabolite of Avermectin B₁a. Accounts for 20% of total soil residue during half-life of 28 to 56 days. The half-life of the metabolite is similar to that of the parent.

⁶ Assuming a small mammal consumes 20% of its body weight per day. Many mammals such as voles, mice, rats, and shrews commonly ingest at least 20% of their weight per day. Exposure may also occur through other routes such as grooming and licking of fur and feet.

Chronic Tests (continued)

Mouse Teratogenic Effects	LEL = 0.2-0.4 mg/kg/day (1-2 ppm ⁶)
Pregnant Mouse 10-day Oral	NOEL = 0.05 mg/kg/day (0.25 ppm ⁶) LEL = 0.075 mg/kg/day (0.375 ppm ⁶)
Mouse Teratogenic with <u>Photodegradate</u>	NOEL = 0.05 mg/kg/day (0.25 ppm ⁶) LEL = 0.1 mg/kg/day (0.5 ppm ⁶)
Avian Reproduction	NOEL = 12 ppm LEL = 64 ppm (reduced egg prod.)
<u>Daphnia magna</u> Life-cycle	MATC >0.03<0.09 ppb (all dead by day 5 at 0.09 ppb)
Rainbow trout Early Life Stage	MATC >0.52<0.96 ppb

Additional Tests

Honey bee (<u>Apis mellifera</u>)	LD ₅₀ = 0.408 ug/bee (highly toxic) .03 lb ai/gal foliar residues (oranges and alfalfa) remain toxic to bees 2 days post- application
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Phytotoxicity

<u>Lemna gibba</u> (duckweed)	14-day EC ₅₀ = 3.9 ppm
<u>Selenastrum capricornutum</u> (freshwater algae)	9-day EC ₅₀ > 100 ppm

Summary of Environmental Fate Information

(from draft Pesticide Fact Sheet No. 84 for Avermectin B₁)

Solubility:	7.8 ppb
Octanol/Water Partition Coefficient:	9.9 X 10 ³
Photolysis:	t ¹ / ₂ < 1 day
Hydrolysis:	minimal
Soil Metabolism:	Aerobic t ¹ / ₂ approx. 2 months Anaerobic is slower
Leaching tendency:	minimal
Bioaccumulation:	Bluegill 69X whole fish 30X fillet 110X viscera
Acute dermal LD ₅₀	> 380 mg/kg - Tox. Category II
Acute inhalation	= 1.62 mg/l - Tox. Category II

There is a 95% loss of accumulated residues in 14 days from fish

after being placed in uncontaminated water. Runoff is expected to be minimal (1% of applied), because of low solubility. An aquatic degradation and fate study⁷ indicated that once it reaches aquatic habitat, avermectin will bind to the sediment and dissipate from the water column generally within two weeks. However, once in the sediment, it may persist with an approximate maximum half-life of 52 days.

Abamectin (MK-936) may persist ~~in~~ the field with a half-life of a month based on a field dissipation study reviewed by EFGWB (EAB) dated September 5, 1985. However, based on another review (August 28, 1985), abamectin has a photolytic half-life of 3.5 to 12 hours.

Terrestrial Exposure

Based on Kenaga, if avermectin is applied at 0.02 lb. ai./acre, the following residues (ppm) may occur on terrestrial food items:

Day 0	Short	Long	Small	Large			
	Grass	Grass	Leafy	Insects	Seed	Insects/	
			Crops	/Forage	Pods	Grain	Fruit
Maximum	4.8	2.2	2.5	1.16	0.24	0.2	0.14
Typical	2.5	1.8	0.7	0.66	0.06	0.06	0.03

6 Weeks Post Application

Maximum	0.6	0.4	0.4	0.02	0.03	0.03	0.03
Typical	0.1	0.2-0.1	<0.2	<0.2	<0.2	<0.2	<0.004

The registrant provided summary residue data from 1986 and 1987 field residue trials on celery. The application rates were according to the maximum recommended use rate. The trials measured avermectin B_{1a} and avermectin B_{1a} delta 8,9-isomer (both as a single component) and avermectin B_{1b} and its delta 8,9-isomer (as a single component), both components assumed to represent the total toxic residues. Ranges of average residues in both 1986 and 1987 trials are given in the Table below. One trial in 1987 also utilized a surfactant (recommended on the label).

⁷ Wislocki, Peter. Degradation of abamectin in a field study simulating both drift and runoff. Report date September 23, 1986; Accession Number 400696-10. From Review dated 3/17/88.

1986 Trials (without surfactant)

Day 0

	<u>Avermectin B_{1a}</u>	<u>Avermectin B_{1b}</u>	<u>Total</u>
Min.	42 ppb (87%)	<5 ppb (13%)	<47 ppb
Max.	498 ppb (92%)	43 ppb (8%)	541 ppb

Day 7

Min.	<5 ppb (71%)	<2 ppb (29%)	<7 ppb
Max.	19 ppb (79%)	<5 ppb (21%)	<24 ppb

1987 Trials (without surfactant)

Day 0

	<u>Avermectin B_{1a}</u>	<u>Avermectin B_{1b}</u>	<u>Total</u>
Min.	106 ppb (91%)	11 ppb (9%)	117 ppb
Max.	309 ppb (91%)	32 ppb (9%)	341 ppb

Day 7

Min.	<5 ppb (71%)	<2 ppb (29%)	<7 ppb
Max.	21 ppb (81%)	<5 ppb (19%)	<26 ppb

1987 Trials (with surfactant - Leaf-Act)

Day 0

	<u>Avermectin B_{1a}</u>	<u>Avermectin B_{1b}</u>	<u>Total</u>
Min.	6.3 ppb (76%)	<2 ppb (24%)	<8.3 ppb
Max.	257 ppb (90%)	27 ppb (10%)	284 ppb

Day 7

Min.	<2 ppb (50%)	<2 ppb (50%)	<4 ppb
Max.	11 ppb (85%)	<2 ppb (15%)	<13 ppb

Comparison of the trial data with the Kenaga table indicates that the maximum measured residues approximate the Kenaga typical value for forage crops (0.66 ppm) immediately after application and approximates the Kenaga maximum residue value for seed pods (six weeks post application) for the 7-day post-application measured values. Use of surfactant decreases these values somewhat. Therefore, the estimated typical residues on forage crops is assumed to be representative of celery and is close to the predicted value for leafy crops considering (multiple applications). Based on past residue data for cotton and citrus other typical values from Kenaga are assumed representative. Since multiple applications are permitted on the label chronic exposure is possible. However, rapid degradation in light ($t_{1/2} < 1$ day) may preclude significant accumulation on food items exposed to light between treatments.

Birds

These residues do not exceed the lowest avian dietary LC₅₀ of 383 ppm nor the avian reproductive NOEL of 12 ppm. Therefore, no acute or chronic hazard to birds is expected.

Mammals

Using an acute oral LD₅₀ of 10 mg/kg for adult rats the following 1-day adult LC₅₀ values (ppm) were calculated⁸ for selected mammals. The weanling 1-day LC₅₀ values were based on a 1.5 mg/kg LD₅₀ for weanling rats. The third column in the table is the extrapolated reproductive LEL's (ppm) based on the rat 1-generation reproductive tests⁹. The weight and food consumption data are from Davis and Golly (1963).

<u>Grazing Herbivores</u>	1-day LC ₅₀ (ppm) <u>adult</u>	<u>weanling</u>	Rep. LEL (ppm)
Meadow vole	16	2.5	0.8
Swamp rabbit	24	3.6	1.2
Deer	412	61.8	20.6
<u>Granivores</u>			
Red squirrel	142	21.3	7.1
<u>Omnivores</u>			
Deer mouse	51	7.7	2.6
Marsh rice rat	218	32.6	10.8
Raccoon	470	70.8	23.6
<u>Insectivores</u>			
Least shrew	9	1.4	0.5
<u>Carnivores</u>			
Least weasel	40	6	2.0

The extrapolated adult LC₅₀ values are not exceeded by the estimated residues on terrestrial food items. The estimated residues on short grasses equals the LC₅₀ for weanling voles. Therefore acute effects may occur to certain young mammals. Based on extrapolated

⁸ LC₅₀ (ppm) = LD₅₀ X wgt. (g) / consumption in 1 day (g).

⁹ Reproductive NOEL (ppm) = rat NOEL X wgt. (g) / consumption in 1-day (g). LEL = 0.5 mg/kg/day; decreased pup survival (76% compared to 98% in controls).

reproductive NOEL's, it is likely that when ingesting food items containing typical residues, grazing herbivores and insectivores of small size would receive greater than their reproductive NOEL. Reproductive NOEL values are approached for omnivores but are not exceeded. Granivores and carnivores would not likely ingest food with residues greater than their reproductive NOEL.

Based on this, it is likely that Avermectin used at 0.02 lb. ai./A would cause acute effects to certain grazing herbivores. Even though avermectin is short lived in light, it is likely that small mammals may experience adverse effects because of multiple applications, food caching (negating photolytic degradation somewhat), and high toxicity. Other routes of exposure include inhalation, absorption through the skin and eyes, and grooming of fur. Further the photodegradate causes mammalian teratogenic effects at lower levels than the parent. Field testing is required to determine if reproductive effects observed in the laboratory will occur in the field.

Aquatic

Because of its low solubility (7.8 ppb), high octanol water partition coefficient (9.9×10^3), and types of soils in which celery is grown, minimal transport of avermectin is expected by runoff. However, erosion of soil into aquatic and estuarine systems and the potential for soil adsorption of avermectin would result in exposure to benthic organisms. Certain cultural practices for celery (cultivation) could enhance soil erosion. Also, exposure to aquatic and estuarine organisms is possible through drift. It is assumed that 5% of the sprayed pesticide drifts, therefore 0.001 lb. ai./A drifts (0.02 lb. ai./A (application rate) \times 0.05 (%)). This would result in concentrations at the following water depths (assuming instantaneous mixing and equilibrium):

<u>Depth</u>	<u>Concentration (ppb)</u>
6 in.	0.734
1 ft.	0.3675
3 ft.	0.122
6 ft.	0.061

These levels are greater than the aquatic invertebrate chronic NOEL of 0.03 ppb. The concentrations in shallow water (up to 1 foot) would exceed the Daphnia magna and shrimp LC_{50} 's (0.22-0.34 and 0.2 ppb, respectively). They also approach or exceed the rainbow trout chronic NOEL (rainbow trout early life stage NOEL = 0.52 ppb). These values do not exceed the fish or oyster acute effect levels.

Avermectin is not expected to be a groundwater concern (based on a field dissipation study reviewed by EFGWB (EAB) dated September 5, 1985). According to the study it remains primarily in the upper 2 inches of soil and even with heavy rainfall (or irrigation) is

not expected to penetrate beyond a soil depth of 4 inches. Therefore effects to subterranean fish and invertebrates is not expected to be a problem where the source of water is primarily from groundwater flows as opposed to surface water flows. —

Summary

Based on the above assessment, aquatic or estuarine invertebrates will experience acute and chronic effects. Risk to non-endangered fish will be minimal. This assessment does not take into account new and unvalidated test results suggesting that avermectin is substantially more toxic to shrimp than previously thought¹⁰. Before EEB can complete risk assessments for aquatic organisms, further information on these tests will be required. Aquatic field testing will be required also.

Non-endangered birds are not expected to experience acute or chronic effects. Neither acute nor chronic risk to large mammals or granivores and carnivores is expected. Weanling rodents (meadow voles) may experience acute and chronic effects, and small grazing herbivores and insectivores would receive greater than their reproductive NOEL. Although chronic effects to omnivores were not exceeded in this review, past reviews have indicated the potential for chronic exposure. Since the chronic values were approached there is potential for chronic exposure to grazing omnivores. This use of avermectin represents a hazard to these mammals. Terrestrial field testing would be required before EEB could conclude safety from this exposure.

101.3 Endangered Species Considerations

The endangered species triggers are as follows:

<u>Group</u>	<u>Trigger (LC₅₀ / 10)</u>	
	<u>Acute</u>	<u>Rep. NOEL</u>
Birds	38.3 ppm	12 ppm
(Reptiles/Terrestrial Amphibians)		
Mammals	0.14 ppm	0.09 ppm

¹⁰ See review dated 3/17/88 which also referenced review of 12-30-87, 96-hour flow-through LC50's of 51 and 11 ppt reported. No information on test has been provided.

<u>Group</u>	Trigger (LC ₅₀ / 20)	
	<u>Acute</u>	<u>Rep. NOEL</u>
Fish	0.32 ppb	0.52 ppb
Aquatic Invertebrates	0.022 ppb	0.03 ppb
Freshwater Mussels	21.5 ppb	not avail.

Terrestrial

Based on Kenaga, if avermectin is applied at 0.02 lb. ai./acre, the following are estimated residues (ppm) on terrestrial food items:

Day 0

	<u>Short</u> <u>Grass</u>	<u>Long</u> <u>Grass</u>	<u>Leafy</u> <u>Crops</u>	<u>Insects</u> <u>/Forage</u>	<u>Seed</u> <u>Pods</u>	<u>Grain</u>	<u>Fruit</u>
Typical	2.5	1.8	0.7	0.66	0.06	0.06	0.03

Maximum residues do not exceed the avian endangered species triggers. Therefore, direct adverse effects to endangered birds (and terrestrial reptiles and amphibians) is not expected. Adverse effects to birds feeding on aquatic invertebrates are likely because of reduced food supply. This could result in effects to the light-footed clapper rail (in southern California)¹¹ and the Everglade snail kite. The light-footed clapper rail feeds opportunistically in salt marshes, probing mud for invertebrates¹². The everglade snail kite feeds only on the apple snail in aquatic habitats.

Adverse effects to fish populations are expected to be minimal and since avermectin does not have a high bioconcentration factor, fish-eating birds (bald eagle, wood stork) are not expected to be impacted.

Maximum residues do exceed both the mammalian acute and chronic triggers. Adverse effects are expected to occur to endangered mammal species exposed to avermectin. Such exposure could occur through ingestion of treated material (celery and non-target plants and insects). This would include grazing herbivores, omnivores, insectivores, and granivores. It is not likely to include carnivores since avermectin does not have a high bioconcentration factor.

¹¹ Contacts and correspondence with Linda Walker, USFWS, Jacksonville, FL, Field Office; Dave Harlow, USFWS, Sacramento, CA, Field Office; and Nancy Kaufman, USFWS, Laguna Niguel, CA, Field Office.

¹² Kaufman, N.M. 1988. Memo to Bill Gill dated Oct. 11, 1988.

However, information in EEB's files and contacts with Fish and Wildlife Service personnel¹¹ in California and Florida did not indicate that any federally listed mammals would be exposed to this use of Avermectin.

Aquatic

The ~~estimated~~ concentrations at all water depths exceed the acute and chronic aquatic invertebrate triggers. The concentrations in shallow water exceed the fish acute trigger (1 foot) and chronic trigger (6 inches). This could effect endangered fish reproduction if exposure occurred. However, information in EEB's files and contacts with Fish and Wildlife Service personnel¹¹ in California and Florida did not indicate that any federally listed fish or invertebrates would be exposed to this use of avermectin.

Based on the Oyster embryo-larvae EC₅₀ of 430 ppb, effects to endangered mussels are unlikely. In addition, no endangered mussels are known to occur in celery growing areas.

Summary

Direct adverse effects to endangered birds are not expected. Adverse effects to aquatic invertebrate food resources of federally listed birds is possible in California¹² (light-footed clapper rail) and Florida (Everglade snail kite). The areal distribution of celery growing areas and Everglade snail kite habitat may preclude exposure to this species' food resource (apple snail)¹³. The extent of exposure to the light-footed clapper rail can not be assessed. Exposure regarding the species' food supply was indicated in southern California¹². However, this species did not receive any jeopardy opinions in the crop cluster consultation. Therefore, significant impact (considering the acreage of celery production compared with other crops (cotton, corn, sorghum, soybeans, and small grains) considered in the crop cluster consultation) on the species' through its food supply, is not anticipated. However, until additional studies are completed clarifying invertebrate toxicity, the extent of these impacts can not be assessed.

Adverse effects to exposed federally listed mammals, invertebrates, and fish may occur. However, no listed mammals, invertebrates, or fish are expected to be exposed to this use of avermectin^{11 12}.

¹³ Florida Department of Agriculture and Consumer Services. 1988. Florida Agricultural Statistics Service Vegetable Summary 1986-87. FL Dept. of Agric. and Consumer Serv., Tallahassee, FL. 70 pp.

101.4 Adequacy of Data

The available data were inadequate to quantify the risks of this proposed registration to both aquatic and terrestrial organisms.

Since the cotton review, the Agency has become aware of additional test results suggesting that Avermectin is much more toxic to shrimp than originally thought. These data were not used to evaluate this proposed registration on celery because they have not been validated. The EEB can not complete risk assessments for celery, citrus, and other major uses until additional data have been provided and the question of toxicity to aquatic organisms in general has been adequately researched. Such testing will require a fish full life cycle test. This test is required since Avermectin is likely to drift into water at levels exceeding 0.1 the fish early life stage NOEL, it will persist in sediment for several months ($t_{1/2} = 52$ days), and it has teratogenic effects on mammals at low levels. The mammalian effects suggest that Avermectin may affect reproduction of other organisms. In addition, aquatic field testing is required to determine if the suggested sensitivity of shrimp is shared by other estuarine and freshwater species, and to determine effects to fish and invertebrates. This should include both mesocosm testing and estuarine studies.

Additional chronic mammalian test results have indicated Avermectin and its photodegradeate affect mouse and rat reproduction at levels likely to be experienced in the field by wild mammals. Field testing is needed to quantify the effects on wild mammals.

101.5 Adequacy of Labeling

Changes in labeling are required by adding the following:

"Do not apply directly to water or wetlands (swamps, bogs, marshes, and pot holes)."

"Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas."

103 Conclusions

The EEB has reviewed the proposed use of Avermectin on celery. Based on available information, EEB concludes that this use is likely to result in acute and chronic adverse effects to mammals, fish, and aquatic invertebrates. Adverse effects to federally listed species are also anticipated. Formal consultation with the U.S. Fish and Wildlife Service is required and will be initiated when acceptable field test results have been submitted and reviewed and prior to registration of this product for use on celery.

Additional data are required to more adequately define the hazards to mammals and aquatic fish and invertebrates such as:

1. Field testing to determine acute and chronic effects on wild mammals. This would involve studying multiple plots to determine acute and chronic effects to small mammals. It is possible that such a study could be designed to address more than one use site;
2. Shrimp life cycle study as well as additional information on the previous data submissions regarding abamectin toxicity to shrimp. The EEB review of 3/8/88 indicates that the shrimp life cycle test was in the process of being performed but no data were received;
3. Fish full life cycle test is required since the EEC exceeds 0.1 the NOEL for the fish early life stage test and avermectin has been shown to have teratogenic effects on mammals and reproductive effects on birds at low levels; and
4. Aquatic field studies to determine effects of Avermectin in aquatic habitats. This study should focus on acute and chronic effects to aquatic invertebrates and chronic effects to fish. It should include residue analysis of organisms as well as measuring individual and population effects. Multiple site estuarine testing is also required to determine the effect of avermectin on shrimp and other estuarine organisms adjacent to celery fields and other uses (e.g., citrus, tomatoes) adjacent to estuarine habitats.

It is recommended that the registrant submit protocols to EEB for review and comment prior to terrestrial and aquatic field testing.

William Gill

1/26/89

William Gill, Wildlife Biologist
Ecological Effects Branch
Environmental Fate and Effects Division

Ray Matheny, Head - Section 1
Ecological Effects Branch
Environmental Fate and Effects Division

Ray W. Matheny 1/26/89

James W. Akerman 1/27/89
James W. Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division